PCT/IL 99/00613
13 DECEMBER 1999

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REC'D 23 DEC 1999
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November 17, 1999 09/183194

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APPLICATION NUMBER: ***60/108,505***
FILING DATE: ***November 16, 1998***

PRIORITY DOCUMENT
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Docket Number: P-2040-USP

PROVISIONAL APPLICATION FOR PATENT COVER SHEET (Large Entity)

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)/APPLICANT(S)		
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☐ *Additional inventors are being named on page 2 attached hereto*

TITLE OF THE INVENTION (280 characters max)

A SENSOR FOR RADIANCE BASED DIAGNOSTICS

CORRESPONDENCE ADDRESS

Direct all correspondence to:

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification	*Number of Pages*	**10**			
☒ Drawing(s)	*Number of Sheets*	**2**	☐ Other (specify)		

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE _____ DATE **11/16/98**

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P19LARGE/REV04

A SENSOR FOR RADIANCE BASED DIAGNOSTICS

Israel SARUSSI

FIELD OF THE INVENTION

The present invention relates to a sensor for radiance based diagnostics of body tissues and to a method for radiance based diagnostics of body tissues.

BACKGROUND OF THE INVENTION

Radiance based diagnostics of body tissues involves radiating a body tissue and obtaining data relating to the transmittance or reflection of the radiated light from the tissue, for analysis of tissue constituents. For example, electro-optical measurement of blood characteristics has been found to be useful in many areas of blood constituent diagnostics, such as glucose levels, oxygen saturation, hematocrit, bilirubin and others. Pulse oximetry is a method for measuring oxygen saturation in the blood, in which two or more wavelengths are radiated through an organ at a point where blood perfuses the organ. Reflective pulse oximetry employs at least one light source and a least one detector which are placed at the same side of an organ. The light source is for radiating the organ and the detector is for receiving the light reflected from the organ. The reflected light is analyzed for measuring the percent of saturated oxygen in the blood.

These methods of body tissue diagnostics usually employ sensors, which are placed on body tissues, and which comprise at least one radiance source for radiating the tissue and at least one radiance detector, for detecting

the rays transmitted through or reflected from the tissue. The accuracy of the results obtained in these methods depends, to a great extent, on ensuring that the detector, or detectors, are exposed only to rays which have passed through the examined tissue and not to other rays, such as rays coming directly form the radiance source.

When a sensor is placed on body tissues, especially on stretched tissues (such as over a bone), or due to irregular tissue surface (such as in wrinkles), there might be a small space between the face of the sensor and the tissue, through which some of the rays can pass directly from the radiance source to the detector, thereby adversely affecting the measurement.

Reference is now made to Fig. 1 which is a schematic side view illustration of a prior art sensor. The sensor, generally referenced 10, contains a light source 12 and a light detector 14. The sensor is placed onto examined tissue 16 and, when operated, light is radiated from light source 12 onto tissue 16. Depending on how the light source 12 is directed, most of the light will pass through the tissue 16 and be partly reflected from the tissue. The reflected light 14' will be received by detector 14 to be analyzed. However, a small fraction of the light 18' radiated from the light source 12 will not pass through the tissue 16 but pass directly to the detector 14, through the small space 18 between the sensor 10 and the tissue 16. Since the detector can not differentiate between the two lights, 14' and 18', the analysis results will be inaccurate.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a sensor for radiance based diagnostics of body tissues, which ensures that only light which has passed through an examined tissue is received by the sensor's detector.

The sensor is comprised of a performing component, which consists of at least one radiance source for radiating a tissue and at least one detector for detecting the rays transmitted through or reflected from the tissue, and of an adhering component, which consists of means for fastening the performing component to an examined body tissue. The adhering component may be a tape of any suitable adhering material, which forms a frame around the performing component or, the adhering component may be a tape, preferably of stretchable material, which overlays the performing component, and which, when adhering to a body tissue, covers the performing component, fastening it to the underlying tissue.

The sensor is designed such that when it is fastened to a tissue and operative, only rays from the light source, which have passed through the examined tissue, are received by the detector. This is achieved by ensuring that, when the sensor is operating, the radiance source and detector are sealed off from each other.

In one embodiment, the sensor is designed such that when placed on an examined tissue, there is no space at all between the performing components, or parts of it, such as the radiance source or the detector, and the examined tissue. In this embodiment, the performing component, or parts of it, protrude from the plane of the adhering component, such that when the sensor is placed on an examined tissue, the adhering component lies on the tissue and

the performing component, or parts of it protrude into the tissue, applying pressure on it. The pressed tissue will serve to seal off the radiance source and detector from each other, or the surface of the performing component, into which the radiance source and detector are embedded, at a distance from each other, may be made of a soft material, such that applying pressure on to the tissue will cause the performing component soft surface to seal off the radiance source from the detector.

In another embodiment, the radiance source is sealed off form the detector by a partition raised between them. When the adhering component is placed on the examined tissue, the partition is pressed to the examined tissue, thereby sealing off the radiance source and the detector from each other.

In yet another embodiment, the sensor comprises means for sensing pressure. These means are for sensing the pressure between a performing component, or between parts of a performing component, and an examined tissue, and for halting the sensor operation, or for alerting an operator if the pressure is not sufficient to achieve sealing off of the radiance source from the detector.

It is another object of the present invention to provide a method for radiance based analysis of body tissues. The method comprises the steps of fastening a sensor to an examined tissue, said sensor being comprised of a performing component, which consists of at least one radiance source for radiating a tissue and at least one detector for detecting the rays absorbed or reflected from the tissue, and of an adhering component, which consists of means for fastening the performing component to an examined body tissue.

The sensor is fastened to the tissue such that the detector does not receive any rays which have not passed through the examined tissue.

BRIEF DESCRIPTION OF THE FIGURES

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Fig. 1 is a schematic side view illustration of a prior art sensor;

Fig. 2A is a schematic under view illustration of the sensor according to an embodiment of the invention, in which the adhering component forms a frame around the performing component;

Fig. 2B is a schematic under view illustration of the sensor according to an embodiment of the invention, in which the adhering component overlays the performing component;

Figs. 3A and 3B are schematic side view illustrations of the sensors of Figs. 2A and 2B operable according to an embodiment of the invention;

Fig. 4A is a schematic under view illustration of the sensor according to an embodiment of the invention, in which the radiance source is separated from the detector by a partition;

Fig. 4B is a schematic under view illustration of the sensor according to an embodiment of the invention, in which the either radiance source or detector or both are separated by a wall; and

Fig. 5 is a schematic side view illustration of the sensor of Fig. 2A, further comprising a pressure detector.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a sensor for radiance based diagnostics of body tissues, which ensures that only light from a light source, which has passed through an examined tissue, is received by the sensor's detector, thereby ensuring higher accuracy of results.

The invention will be described in reference to reflective pulse oximetry, but it will be appreciated by persons skilled in the art that the invention relates to any radiance based method of diagnosing body tissues, reflective or other. The light source and detector, may, therefore, be situated on the same side of the examined tissue or on opposing sides, according to the diagnostic method used. The terms light source and detector, in the present invention, relate to one or more light source or detector. Furthermore, the term light source, in the present invention, refers to a radiance source which is not limited to visible light but may radiate in any wavelength which is suitable for the specific method used.

Reference is now made to Figs. 2A and 2B which are schematic under view illustrations of a sensor, generally referenced 20. The sensor 20 comprises a performing component 21, which consists of a light source 22 for radiating a tissue and a detector 24 for detecting the rays reflected from the tissue, and of an adhering component 23, which may be disposable. In Fig. 2A the adhering component 23 is an adhesive tape forming a frame around the performing component 21, for fastening the performing component to an examined body tissue, and for keeping it in place. In Fig. 2B the adhering component 23 is a tape, preferably of stretchable material, which overlays the

performing component, and which, when adhering to a body tissue, covers the performing component, fastening it to the underlying tissue.

The detector 24 may perform analysis of the light received by it, light which has been passed through the examined tissue, for obtaining data related to constituents of the examined tissue, such as measuring the percent of saturated oxygen in the blood.

The performing component 21 may be powered through a cable 26 (shown only in Fig. 2B).

Reference is now made to Figs. 3A and 3B which are schematic side view illustrations of a sensor operable according to the invention. It can be seen from these figures that when the sensor, generally referenced 30, is placed on a body tissue 35, the performing component 31 protrudes from the plane of the adhering component 33, in the direction of the tissue 35, such that when the adhering component 33 is placed in contact with the tissue 35, the performing component 31 presses into the tissue forming indentation 35'. It can further be seen that adhering component 33 is in contact with performing component 31, such that, the adhering component surface 33' is essentially parallel to the performing component surface 31'. Accordingly, when sensor 30 is fastened to tissue 35, there is not any empty space at the connection point 37 between the adhering component 33, the performing component 31 and the tissue 35, whereby light cannot reach the detector 34 either from the outside or directly from the light source 32.

The pressure exerted by performing component 31 on the tissue, fastens the light source and detector (not shown) to the tissue so that rays

emitted from the light source, are unable to reach the detector through any other medium, but the tissue.

The surface of the performing component 31 is usually, but not always, a printed circuit. The performing component surface can be coated or overlaid with a soft layer, such as a silicone or sponge layer. The soft layer will contribute to sealing off of the light source from the detector when the sensor is pressed onto the tissue.

Reference is now made to Figs 4A and 4B which are schematic under view illustrations of a sensor, generally referenced 40. In this embodiment the performing component 41 of the sensor 40 comprises a raised partition 46 in between the light source 42 and the detector 44. The partition 46 may also be a wall 46' surrounding either the light source 42 or the detector 44, or both, while separating them from each other (shown in Fig. 4B). When sensor 40 will be fastened to a body tissue (as described in Figs. 3A and 3B) by adhering component 43, partition 46, which is raised above the plane of the sensor 40, will exert pressure on the tissue and thus will seal off the detector 44 from the light source 42.

Reference is now made to Fig. 5 which is a schematic illustration of a sensor generally referenced 50, which further comprises a pressure detector 56. Pressure detector 56, in this figure, is a micro switch which responds to mechanical pressure, but may be any suitable sensor for sensing either a proximity or an actual pressure between the tissue 55 and the performing component 51, or between the tissue 55 and parts of the performing component 51, such as the light source 52 or the detector 54. The pressure detector 56 may indicate to an operator, if the proximity or pressure between

the performing component 51, or parts of it, is insufficient to seal off the light source 52 from the detector 54, so that the operator may remedy the situation. The Pressure detector 58 may also shut off light detector 52 , if insufficient proximity or pressure is detected by it.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described herein above. Rather the scope of the invention is defined by the claims which follow:

CLAIMS

1. A sensor, for radiance based diagnosticsis, comprising

a performing component and an adhering component

said performing component comprising at least one radiance source for radiating a tissue and at least one detector for detecting rays emitted from said radiance source which are transmitted through or reflected from the tissue, and

said adhering component comprising means for fastening the performing component to an examined body tissue.

wherein, when operative, the radiance source and detector are sealed off from each other.

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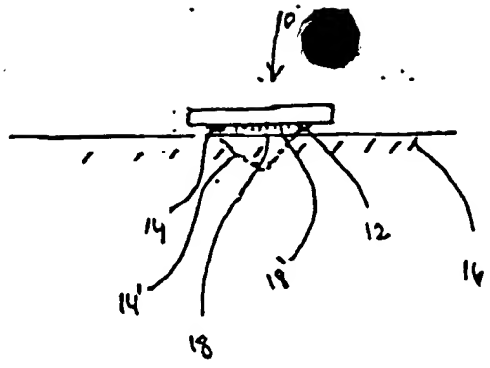
FIG 1



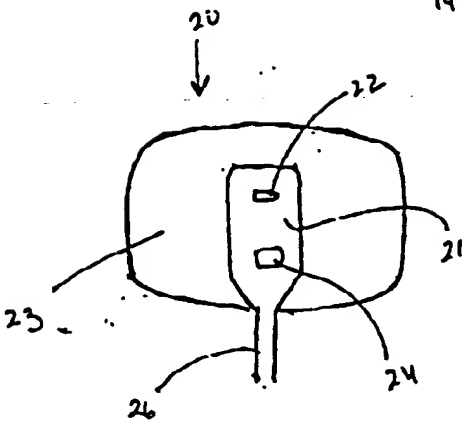


Fig. 2B

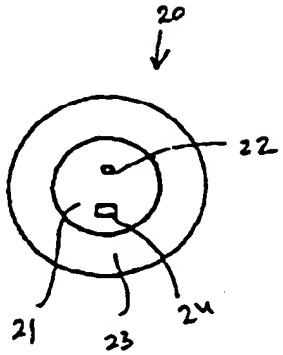


Fig 2A

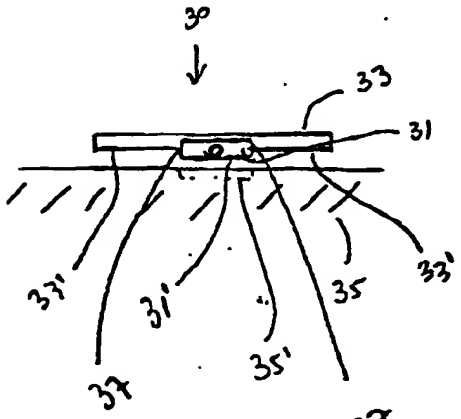


Fig. 3B

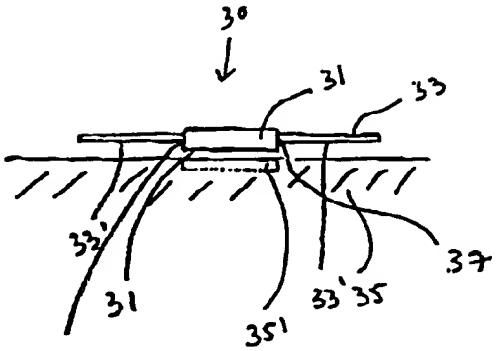


Fig 3A

Fig. 4B

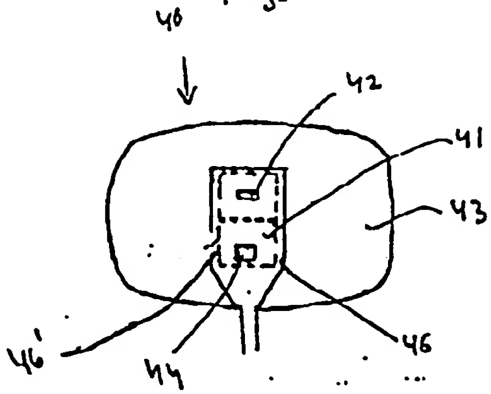
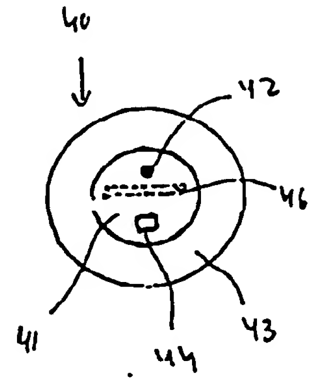


Fig. 4A



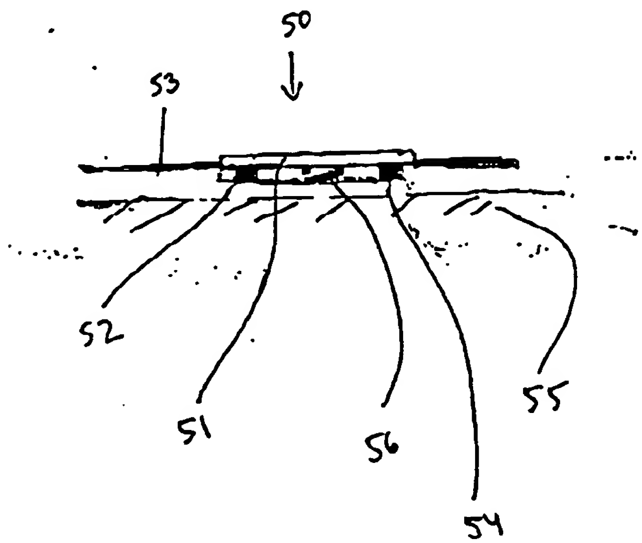


Fig. 5